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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick Gattari on December 15, 2010.

The application has been amended as follows:

In the specification:

In paragraph [0013], line 7, "POLYBREEN" has been changed to --POLYBRENE--.

In the claims:

Claim 1, lines 9-10, "amount of free fraction of thrombin ," has been changed to --thrombin activity in the reaction mixture,--

Claim 1, line 13, "amount of the free fraction of thrombin" has been changed to --thrombin activity--.

Claim 1, line 16, the word "thrombin," has been changed to --thrombin activity,--

Claim 5 has been canceled without prejudice.

Claim 17, line 6, the words "if present," have been deleted.

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Claim 17, line 8, “amount of a free fraction of thrombin,” has been changed to --thrombin activity in the reaction mixture,--

Claim 17, line 11, “for the free fraction of thrombin” has been changed to --of the thrombin activity--.

2. The following is an examiner’s statement of reasons for allowance: upon reconsideration of the evidence currently of record, the examiner finds that the teachings of Plattner et al. (or Philo et al.) in view of Winant et al., Furatu, Morris et al., and Akhavan-Tafti et al. fail to fairly teach the claimed invention.

In particular, Exhibit I of the instant Reply filed 7/6/2010 (Beeck et al.) teaches that “[t]hrombin-based assays must not be used in patients under treatment with hirudin or other direct thrombin inhibitors” (see last sentence of the abstract). This provides evidence of non-obviousness of the claimed invention, which is a thrombin-based assay performed on samples that may contain thrombin inhibitors. For these reasons and when taken together with the declaration evidence under 37 CFR 1.132 by Dr. Adema also filed 7/6/2010, the claims are not obvious over the cited references.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571)272-8786. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/
Examiner, Art Unit 1641

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

12/17/10